



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

January 29, 2016

Mr. Jamie Staley  
U.S. Registration Manager  
Pioneer Hi-Bred International, Inc.  
7100 NW 62<sup>nd</sup> Avenue  
Johnston, Iowa 50131

Subject: Optimum<sup>®</sup> TRIsect<sup>™</sup>  
EPA Registration Number: 29964-13  
Submission to amend the expiration date of the registration  
Submission dated December 14, 2015  
Decision No. 513110

Dear Mr. Staley:

The amendment referred to above, submitted in connection with registration under Section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable only as an amendment to the current conditional registration, and provided that you comply with the updated terms and conditions as described in this letter.

- 1] The subject registration will automatically expire on midnight March 31, 2016.
- 2] The subject registration will be limited to Cry1F [*Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (plasmid insert PHP8999A) in event TC1507 corn (OECD Unique Identifier: DAS-Ø15Ø7-1)] x [mCry3A (MIR604) corn with modified Cry3A protein and the genetic material necessary for its production (via elements of vector pZM26) in corn SYN-IR6Ø4-5] for use in field corn.
- 3] Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when the Environmental Protection Agency (EPA) requires registrants of similar products to submit such data.
- 4] Submit/cite all data, determined by EPA to be acceptable and required to support the individual plant-incorporated protectants in Herculex<sup>®</sup> I Insect Protection, within the time frames required by the terms and conditions of EPA Registration Number 29964-3.
- 5] This plant-incorporated protectant (PIP) may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and

hybrid corn varieties with combined pesticidal traits.

6] You must commit to do the following Insect Resistance Management (IRM) Program, consisting of the following elements:

- Requirements for Pioneer Hi-Bred International, Inc. (Pioneer) to implement an IPM-based stewardship program designed to reduce selection pressure for corn rootworm (CRW) resistance.
- Requirements relating to creation of a refuge for the Cry1F and mCry3A components that meets the requirements of the individual traits. The refuge for both traits may be combined by planting non-*Bacillus thuringiensis* (*Bt*) corn as the refuge, or the refuge for each trait may be planted separately. In the latter case, corn rootworm resistant *Bt* corn may be planted in the lepidopteran refuge for the Cry1F component, and lepidopteran-resistant *Bt* corn may be planted in the corn rootworm refuge for the mCry3A component.
- Requirements for Pioneer Hi-Bred International, Incorporated (Pioneer) to prepare and require Optimum® TRIsect™ corn users to sign grower agreements that impose binding contractual obligations on growers to comply with the refuge requirements.
- Requirements for Pioneer to develop, implement, and report to EPA on programs to educate growers about IRM requirements.
- Requirements for Pioneer to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements.
- Requirements for Pioneer to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to the Cry1F protein in the target insects.
- Requirements for Pioneer to develop, and if triggered, to implement a remedial action plan that would contain measures Pioneer would take in the event that any field-relevant insect resistance to Cry1F was detected, as well as to report on activity under the plan to EPA.
- Requirements for Pioneer to investigate reports of unexpected CRW damage to Optimum® TRIsect™ corn from growers ("performance inquiries") and sample CRW to determine if the insects are resistant to mCry3A.
- Requirements for Pioneer to recommend CRW management options to growers in response to cases of unexpected CRW damage to Optimum® TRIsect™ corn.
- Requirements regarding mitigation and notification actions that Pioneer would take in the event that CRW resistance was detected.
- Requirements for Pioneer to maintain, and provide the Agency upon request, the number of units sold by state and county, IRM grower agreement results, and substantive changes to educational programs.

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Pioneer is required to submit reports within three months of the Agency's request.

- Requirements for Pioneer, on or before August 31<sup>st</sup> of each year, to submit reports on Cry1F resistance monitoring.

**a. Integrated Pest Management Stewardship Program**

1) Pioneer must implement an IPM-based stewardship program for Optimum® TRIsect™ corn. This program must be designed to reduce selection pressure for corn rootworm (CRW) resistance by encouraging growers to engage in a multi-year crop rotation strategy involving the use of one or more of the following: a non-CRW host crop (e.g., soybean), pyramided Bt corn Plant Incorporated Protectants (PIPs), other PIP corn products with different modes of action, and/or non-Bt or non-CRW protected Bt corn. As part of the stewardship program, Pioneer must update the technology use guide/grower guide and other grower educational materials to indicate that the use of soil-applied insecticides (SAI) with Optimum® TRIsect™ corn is not recommended for control of CRW except under limited circumstances and in consultation with extension, crop consultants or other local experts. A copy of the revised grower educational materials must be provided to EPA by January 31, 2017 (provided the registration is extended beyond this date). As part of the stewardship program, Pioneer must promote the ABSTC/NCGA Best Management Practices (BMPs) for CRW control. Implementation of the IPM strategy can include:

- Grower education initiatives or incentives;
- Outreach to extension and consultant groups.

2) Pioneer must submit an annual report to EPA documenting activities conducted under the IPM stewardship program. This report must include an anonymous survey of grower practices, including adoption levels of the various crop rotation options (if employed) and other elements of the stewardship program. Pioneer may combine this product with other registered products to submit one annual report. The report must be submitted by January 31<sup>st</sup> each year, beginning in 2017 (provided the registration is extended beyond this date). The 2017 report will serve as a baseline unless Pioneer wishes to submit a separate baseline report prior to January 31, 2017.

**b. Refuge Requirements for Optimum® TRIsect™ Corn**

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per PIP active ingredient per registrant per year.

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance will be provided by Pioneer to help these growers meet the refuge requirements across their farming operations.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the refuge requirements as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

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The use of Optimum® TRIsect™ corn requires accompanying refuge corn for both the Cry1F and mCry3A components that meets the requirements of the individual traits, as described below. The refuge for both traits may be combined by planting non-*Bt* corn as the refuge (see the “Combined Refuge Option” section), or the refuge for each trait may be planted separately (see the “Lepidopteran Refuge for the Cry1F Component” and “Corn Rootworm Refuge for the mCry3A Component” sections).

For the separate refuges, corn rootworm-resistant *Bt* corn (e.g., Herculex® Rootworm Insect Protection) may be planted in the lepidopteran refuge for the Cry1F component, and lepidopteran-resistant *Bt* corn (e.g., Herculex® I Insect Protection) may be planted in the corn rootworm refuge for the mCry3A component. Depending on cropping practices, pest problems, and pest management options employed on any given farm, growers may need to choose different refuge arrangements for different fields. Two refuge blocks (one for rootworm, one for Lepidoptera) can be planted within one field, or strips can be used for either refuge. Alternatively, a block of Herculex® Rootworm Insect Protection corn can serve as an in-field lepidopteran refuge for one field planted to Optimum® TRIsect™ corn and an external lepidopteran refuge for separate fields planted to Optimum® TRIsect™ corn, while the rootworm refuge is planted as Herculex® I Insect Protection corn in an external adjacent field. In all options, size and management of each individual refuge must be followed as described in the “Lepidopteran Refuge for the Cry1F Component” and “Corn Rootworm Refuge for the mCry3A Component” sections.

Other refuge designs and combinations are permissible as long as, in all cases, the size and management of each refuge are described in the “Lepidopteran Refuge for the Cry1F Component,” “Corn Rootworm Refuge for the mCry3A Component,” or “Combined Refuge Option” sections.

#### Lepidopteran Refuge for the Cry1F Component

1] *Refuge size, Corn-growing areas (Corn Belt and other non-corn/cotton-growing areas).* The use of Optimum® TRIsect™ corn requires an accompanying 20% refuge consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.

2] *\*Refuge size, Corn/cotton-growing areas.* The use of Optimum® TRIsect™ corn requires an accompanying 50% refuge consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.

3] *Refuge location.* The lepidopteran refuge can be planted in a separate field not more than ½ mile from the Optimum® TRIsect™ corn field.

The lepidopteran refuge can be planted within the Optimum® TRIsect™ corn field as blocks (e.g., along the edges or headlands).

The lepidopteran refuge can be planted within the Optimum® TRIsect™ corn field as strips across the field at least four (4) consecutive rows wide.

4] *Refuge management.* Insecticide treatment for European corn borer (ECB), corn earworm (CEW), southwestern corn borer (SWCB), and other lepidopteran pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for 1 or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g.,

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Extension Service agents or crop consultants). Instructions to growers will specify that microbial *Bt* insecticides must not be applied to refuges consisting of non-*Bt* corn or corn that is not a lepidopteran-protected *Bt* hybrid.

\*Cotton-growing areas include the following states: Alabama, Arkansas, Florida, Georgia, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

#### Corn Rootworm Refuge for the mCry3A Component

1] *Refuge size*. The use of Optimum® TRIsect™ corn requires an accompanying 20% refuge consisting of non-*Bt* corn or corn that is not a rootworm-protected *Bt* hybrid.

2] *Refuge location*. The rootworm refuge is required to be planted within or adjacent (e.g., across the road) to the Optimum® TRIsect™ corn field.

3] *Refuge management options*. The rootworm refuge can be managed in such a way that there is little or no yield loss to rootworms, but must be managed in a way that it is sufficiently productive of susceptible rootworm adults.

The in-field rootworm refuge options must be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide.

Seed mixtures of Optimum® TRIsect™ and rootworm refuge corn are not permitted.

If the rootworm refuge is planted on rotated ground, then Optimum® TRIsect™ corn must also be planted on rotated ground.

If the rootworm refuge is planted in continuous corn, the Optimum® TRIsect™ corn field may be planted on either continuous or rotated land (option encouraged where western corn rootworm rotation-resistant biotype may be present).

Application of soil insecticide is permitted in the rootworm refuge.

Seed treatment is permitted in the rootworm refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.

If aerial insecticides are applied to the rootworm refuge for control of corn rootworm adults, the same treatment must also be applied in the same time frame to Optimum® TRIsect™ corn.

Pests other than adult corn rootworms can be treated on the rootworm refuge acres without treating the

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Optimum® TRIsect™ corn acres only if treatment occurs when adult corn rootworms are not present or if pesticide without activity against adult corn rootworms is used. Pests on the Optimum® TRIsect™ corn acres can be treated as needed without having to treat the rootworm refuge.

The rootworm refuge can be planted to any corn hybrid that does not express plant incorporated protectants for rootworm control (e.g., lepidopteran-protected *Bt* corn, herbicide-tolerant corn, or conventional corn).

The rootworm refuge and Optimum® TRIsect™ corn should be sown on the same day, or with the shortest window possible between planting dates, to ensure that corn root development is similar among varieties.

Growers are encouraged to plant the rootworm refuge in the same location each year, as it allows the rootworm population to remain high and the durability of the trait is extended. This option may be preferable to growers who wish to only think of their refuge design once and for growers who grow continuous corn; however, for those growers who need to employ crop rotation, a fixed refuge would be impractical.

#### Combined Refuge Option

For the combined refuge option (i.e., the lepidopteran refuge combined with the rootworm refuge by planting non-*Bt* corn), the refuge must be planted and managed such that it is consistent with the requirements of the individual traits, Cry1F and mCry3A.

1] *Refuge size.* The use of Optimum® TRIsect™ corn requires an accompanying 20% refuge in corn-growing areas and 50% refuge in cotton-growing areas consisting of non-*Bt* corn. For the latter, see the list of states labeled with "\*" in the "Lepidopteran Refuge for the Cry1F Component" section.

2] *Refuge location.* The combined refuge is required to be planted within or adjacent (e.g., across the road) to the Optimum® TRIsect™ corn field.

3] *Refuge management options.* The in-field combined refuge options must be planted as a single block or as a series of strips measuring at least four (4) consecutive crop rows wide.

Seed mixtures of Optimum® TRIsect™ and combined refuge corn are not permitted.

If the combined refuge is planted on rotated ground, then Optimum® TRIsect™ corn must also be planted on rotated ground.

If the combined refuge is planted in continuous corn, then Optimum® TRIsect™ corn field may be planted on either continuous or rotated land (option encouraged where western corn rootworm rotation-resistant biotype may be present).

Application of soil insecticide for corn rootworm control is permitted in the combined refuge.

Seed treatment is permitted in the combined refuge, either at a rate for rootworm protection or at a rate for controlling secondary soil pests.

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If aerial insecticides are applied to the combined refuge for control of corn rootworm adults, the same treatment must also be applied in the same time frame to Optimum® TRIsect™ corn.

Insecticide treatments in the combined refuge for control of ECB, CEW, SWCB, and other lepidopteran pests listed on the label, grower guides, or other educational material may be applied only if economic thresholds are reached for one (1) or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). These pests can be treated with corn rootworm-labeled insecticide on the combined refuge acres without treating the Optimum® TRIsect™ corn acres only if treatment occurs when adult corn rootworms are not present. Instructions to growers will specify that microbial *Bt* insecticides must not be applied to the combined refuges.

Pests other than adult corn rootworms can be treated with corn rootworm-labeled insecticide on the combined refuge acres without treating the Optimum® TRIsect™ corn acres only if treatment occurs when adult corn rootworms are not present. Pests on the Optimum® TRIsect™ corn acres can be treated as needed without having to treat the combined refuge.

The combined refuge can be planted to any corn hybrid that does not express plant incorporated protectants for lepidopteran or rootworm control (i.e., herbicide-tolerant corn or conventional corn).

The combined refuge and Optimum® TRIsect™ corn should be sown on the same day, or with the shortest window possible between planting dates, to ensure that corn root development is similar among varieties.

#### **c. Grower Agreements for Optimum® TRIsect™ Corn**

- 1] Persons purchasing Optimum® TRIsect™ corn must sign a grower agreement. The term grower agreement refers to any grower purchase contract, license agreement, or similar legal document.
- 2] The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3] Pioneer must continue to integrate this registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Optimum® TRIsect™ corn will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4] Pioneer must continue to use its current grower agreement for Optimum® TRIsect™ corn. If Pioneer wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty (30) days prior to implementing a proposed change, Pioneer must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of this registration.
- 5] Pioneer must integrate this registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Optimum® TRIsect™ corn sign grower

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agreement(s).

6] Pioneer shall maintain records of all Optimum® TRIsect™ corn grower agreements for a period of three (3) years from December 31<sup>st</sup> of the year in which the agreement was signed.

7] Pioneer shall make available to the Agency upon request records of the number of units of Optimum® TRIsect™ corn seed sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements for the previous growing season. Pioneer is required to submit reports within three months of the Agency's request.

8] Pioneer must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license numbers of the growers, will be protected.

**d. IRM Education and Compliance Monitoring Programs for Optimum® TRIsect™ Corn**

1] Pioneer must continue to implement and enhance (as set forth in paragraph 17 of this section) a comprehensive, ongoing IRM education program designed to convey to Optimum® TRIsect™ corn users the importance of complying with the IRM program. The program shall include information encouraging Optimum® TRIsect™ corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Optimum® TRIsect™ corn fields. The education program shall involve the use of multiple media (e.g., face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials). Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each Optimum® TRIsect™ corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Pioneer shall coordinate its education programs with educational efforts of other registrants and organizations, such as the National Corn Growers Association and state extension programs.

2] Annually, Pioneer shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey, required under paragraph 6-10 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3] Upon EPA request, Pioneer shall provide copies of grower education materials and information on grower education activities including any substantive changes to these materials and activities conducted either individually or as part of the industry working group, Agricultural Biotechnology Stewardship Technical Committee (ABSTC). The required features of the compliance assurance program are described in paragraphs 4-22 of this section.

4] Pioneer must continue to implement and improve an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing Optimum® TRIsect™ corn are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to Pioneer's *Bt* corn products. Pioneer shall coordinate with other *Bt* corn registrants in improving its compliance assurance program and integrate this registration into the current compliance assurance program used for its other *Bt* corn plant-incorporated



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protectants. Other required features of the program are described in paragraphs 5–22 of this section.

5] Pioneer must maintain and publicize a phased compliance approach (i.e., a guidance document that indicates how it will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any noncompliant growers after the first year of non-compliance). While recognizing that for reasons of difference in business practices there are needs for flexibility between different companies, Pioneer must use a consistent set of standards for responding to non-compliance. An individual grower found to be significantly out of compliance two (2) years in a row would be denied access to Pioneer's *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

6) The IRM compliance assurance program shall include an annual survey, conducted by an independent third party, of a statistically representative sample of growers of Optimum® TRIsect™ corn who plant the vast majority of all corn in the United States and in areas in which the selection intensity is greatest. The survey shall consider only those growers who plant 200 or more acres of corn in the Corn Belt and who plant 100 or more acres of corn in corn/cotton areas. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from independent marketing research firms and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the United States.

i. A third party is classified as a party other than the registrant, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.

7] The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

8] The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.

9] Pioneer shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA on or before January 31<sup>st</sup> of each year. Pioneer shall confer with other registrants and EPA on the design and content of the survey prior to its implementation.

10] Annually, Pioneer shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey, required under paragraphs 6–9 of this section, and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Pioneer must confer with EPA prior to adopting any changes.

11] Pioneer shall conduct an annual on-farm assessment program. Pioneer shall train its representatives who make on-farm visits with Optimum® TRIsect™ corn growers to perform assessments of compliance with IRM requirements. There is no minimum corn acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits result in the identification of a

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grower who is not in compliance with the IRM program, Pioneer shall take appropriate action, consistent with its phased compliance approach, to promote compliance.

12] Pioneer shall carry out a program for investigating legitimate tips and complaints that Optimum® TRIsect™ corn growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Pioneer shall take appropriate action, consistent with its phased compliance approach.

13] If a grower, who purchases Optimum® TRIsect™ corn for planting, was specifically identified as not being in compliance during the previous year, Pioneer shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.

14] Annually, Pioneer shall provide a report to EPA summarizing the activities carried out under its compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. Within one (1) month of submitting this report to EPA, Pioneer shall meet with EPA to discuss its findings. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements. Pioneer may elect to coordinate information with other registrants and report collectively the results of compliance assurance programs.

15] Pioneer and the seed corn dealers for Pioneer must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license numbers of the growers, will be protected.

16] Pioneer shall continue to revise and expand its existing compliance assurance program to address refuge requirements. Pioneer may coordinate with other registrants in designing and implementing its compliance assurance program.

17] Pioneer will enhance the refuge education program throughout the seed delivery channel to:

- i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge.
- ii. Include the refuge size requirement on all Optimum® TRIsect™ corn seed bags or bag tags. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics.

18] Pioneer will focus the majority of on-farm assessments on regions with the greatest risk for resistance:

- i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest.
- ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where Optimum® TRIsect™ corn is used.

19] Pioneer will use its available Optimum® TRIsect™ corn sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements to:

i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased Optimum® TRIsect™ corn but may have purchased little or no refuge seed from the registrant, licensees, or affiliated companies.

20] Pioneer will contract with third parties to perform on-farm assessments of compliance with refuge requirements:

i. The third-party assessors will conduct all first-time on-farm assessments, as well as second-year on-farm assessments, of those growers found out of compliance in a first-time assessment.

21] Annually, Pioneer will refine the on-farm assessment program for Optimum® TRIsect™ corn to reflect the adoption rate and level of refuge compliance for Optimum® TRIsect™ corn.

22] Pioneer will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:

i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of two (2) years by Pioneer, a seed supplier, or a third party assessor, after completing the assessment process.

ii. Pioneer will conduct follow-up checks on growers found to be significantly out of compliance within three (3) years after they are found to be back in compliance.

iii. A grower found with a second incident of significant non-compliance with refuge requirements for Optimum® TRIsect™ corn within a 5-year period will be denied access to Pioneer's *Bt* corn products the next year.

**e. Insect Resistance Monitoring and Mitigation Plan for Optimum® TRIsect™ Corn**

**1] EPA is imposing the following conditions for the Cry1F toxin expressed in Optimum® TRIsect™ corn.**

Pioneer will monitor for resistance to Cry1F expressed in Optimum® TRIsect™ corn. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing; and (2) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

**Focused Population Sampling**

Pioneer shall annually sample and bioassay populations of the key target pests: *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (southwestern corn borer; SWCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk

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of resistance development (e.g., where lepidopteran active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to Optimum® TRIsect™ corn and/or changes in resistance allele frequency in response to the use of Optimum® TRIsect™ corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of twelve (12) populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six (6) populations. For CEW, the target will be a minimum of ten (10) populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of Optimum® TRIsect™ corn. EPA shall be consulted prior to the implementation of such modifications.

Pioneer will report to EPA, on or before August 31st of each year, the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the Cry1F protein in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to EPA annually on or before August 31st. The investigative steps will include the following:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.
2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to Optimum® TRIsect™ corn under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.
3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include the following:
  - Determining the nature of the resistance (i.e., recessive or dominant, and the level of functional dominance); estimating the resistance allele frequency in the original population;
  - Determining whether the resistance allele frequency is increasing by analyzing field collections in

subsequent years sampled from the same site where the resistance allele(s) was originally collected;

- Determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Pioneer will consult with EPA to develop and implement a case-specific resistance management action plan.

#### Investigation of Reports of Unexpected Levels of Damage by the Target Pests

Pioneer will follow up on grower, extension specialist, or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Pioneer will instruct its customers to contact them if such incidents occur. Pioneer will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), Pioneer will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

#### *Suspected Resistance*

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect-feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and
- that there could be no other reasonable causes for the damage.

EPA does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does EPA intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to Optimum® TRIsect™ corn in commercial production fields before responsive measures are undertaken.

If resistance is *suspected*, Pioneer will instruct growers to do the following:

- Use alternative control measures in Optimum® TRIsect™ corn fields in the affected region to control the target pest during the immediate growing season.

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- Destroy Optimum® TRIssect™ corn crop residues in the affected region within one (1) month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residues, Pioneer will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

### ***Confirmed Resistance***

EPA defines ***confirmed resistance*** to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of  $\geq 0.1$  in the sampled population.
- In standardized laboratory bioassays, the  $LC_{50}$  exceeds the upper limit of the 95% confidence interval of the  $LC_{50}$  for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

### **Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field**

When field resistance is ***confirmed*** (as defined above), the following steps will be taken by Pioneer:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;
- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn

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hybrids in the affected area immediately until an effective local mitigation plan, approved by EPA, has been implemented;

- Pioneer will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Pioneer will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;
- Pioneer will notify affected parties (e.g., growers, consultants, extension agents, seed distributors, university cooperators, and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to EPA, on or before August 31<sup>st</sup> of each year, for the duration of the registration.

**2) EPA is imposing the following conditions for the mCry3A toxin expressed in Optimum® TRIsect™ corn:**

**a) Investigation of Reports of Unexpected Levels of Damage (UXD) by Corn Rootworm (CRW): Performance Inquiries**

- 1) Pioneer is required to investigate "performance inquiries" (i.e., reports of unexpected CRW damage to Optimum® TRIsect™ corn) from growers. Fields (defined as a tract separated by permanent boundaries such as fences, permanent waterways, woodlands, croplines not subject to change because of farming practices, or other similar features) with unexpected damage that meet both of the criteria below must be subjected to the follow-up actions in part 2) below:
  - i. The affected plants are confirmed to be Optimum® TRIsect™ corn plants (take leaf samples to determine the presence of the CRW-active Bt protein); and
  - ii. Corn rootworm feeding caused root damage with a Node Injury Score (NIS) > 1.0 on at least 50% of plants surveyed in a transect sampling of the damaged site(s) within the field.
- 2) Follow-up actions (performance inquiries). For Optimum® TRIsect™ corn fields meeting the criteria in part 1) above, Pioneer must take the following actions:
  - Collect at least 250 (ideally 500 or more) CRW adult individuals from the damaged site within the field in question. Collections may be extended to the whole field, if necessary to obtain sufficient CRW adult individuals. Collected populations must be subjected to the steps described for "investigation of populations of concern" in section e(2)(b) below.

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- If collections are unsuccessful, visit affected farm or field the following year (assuming the grower continues to be a customer and repurchases seed and does not rotate the field to a non-host crop) and attempt to collect CRW adults. If beetles are not present the subsequent year, see section e(2)(b)(3)(c) below.
- Review with the grower their CRW management practices and provide CRW management recommendations including an assessment of corn fields with similar trait(s) adjacent to the affected corn field that are managed by the same grower.
- Use of single trait products containing the CRW trait in fields with unexpected damage in previous years should be discouraged. Recommended management options include, but are not limited to, the following:
  - Primary option: Rotation to non-host crop (e.g., soybean)
  - Secondary options:
    - Use of pyramided Bt corn products with multiple CRW PIP traits
    - Use of different single-CRW PIP traits (i.e., an alternative CRW-active PIP)
    - Use of non-Bt or non-CRW protected corn
  - Tertiary options: If additional pest management need is determined beyond the secondary options listed above, additional CRW control tools (e.g., soil insecticides, seed-applied insecticides, chemigation) should be used
- If field(s) with UXD is/are planted to a non-host crop (e.g., soybean) the following year, then the area will be considered "mitigated" (as discussed in section e(2)(b)(3)(d) below) even if subsequent bioassay results show that the population was resistant. No further action will be required by Pioneer for the UXD case.

3) Pioneer must submit an annual report to EPA detailing activities related to investigations of unexpected damage (UXD). This report will include the information from the most recent and previous corn growing seasons:

- i. Information from the most recent season:
  - The number of UXD reports investigated.
  - Location (by county and state).
  - CRW sampling (number and location of populations collected).
- ii. Information from the previous season:
  - The final disposition of UXD fields from the previous season (i.e., the management practices employed in response to UXD if the grower continues to be a customer.
  - Results from bioassays conducted on CRW populations from UXD fields where the primary management option, rotation to non-host crop, was not used.
- iii. Grower information, such as farm addresses or other personally identifiable information, or other sensitive business/customer information must not be included in this report. This report must be submitted by November 30<sup>th</sup> each year.

#### b) Investigation of Populations of Concern



- 1) Pioneer must conduct investigations of all CRW populations collected as part of the performance inquiry process in section e(2)(a) above. These investigations must include the use of an EPA-approved bioassay to determine if sampled CRW populations are resistant to mCry3A. Acceptable assays must be able to function as diagnostic tools capable of distinguishing resistant populations from susceptible ones. Unless previously approved, Pioneer must consult with EPA on their bioassay prior to its use.
- 2) A CRW population will be considered by EPA to be resistant to mCry3A if the following criteria are met and additional collections and testing are not deemed to be necessary (based on part 3) below):
  - a. An initial performance inquiry investigation results in a finding of Unexpected Damage; and
  - b. Where green tissues are available and if plants are unusually stressed due to agronomic and/or environmental factors, Bt protein levels in affected plants are found to be within the documented range for that hybrid (if data are available); and
  - c. Either (A): On-plant bioassays of insect collections from the UXD fields result in the following two statistically relevant comparisons
    - i. A statistically significant difference in measures of either mortality or sublethal effects (growth/development) between the field population and a relevant susceptible control population (i.e., one that responds as a typical susceptible field population) on Bt corn and/or lack of a statistically significant difference in measures of mortality or sublethal effect between the field population and a resistant positive control population<sup>†</sup>; and
    - ii. A lack of a statistically significant difference in the same measures of the field population raised on Bt corn and non-Bt corn plants.Or (B): Sublethal seedling bioassay of insect collections from the UXD fields result in two statistically relevant comparisons
    - i. A statistically significant difference in measures of sublethal effects (growth/development) for populations on Bt corn (normalized using non-Bt) seedlings between the field population and a relevant susceptible control population where available or historical field populations and/or lack of a statistically significant difference in measures between the field population and a resistant positive control population<sup>†</sup>; and
    - ii. A lack of a statistically significant difference in the same measures of the field population raised on Bt corn seedlings and non-Bt corn seedlings.Or (C): Diet-based bioassays of insect collections from the UXD fields result in two statistically relevant comparisons
    - i. A statistically significant difference in measures of lethal or sublethal effects (growth/development) on diet containing the Bt protein (diagnostic concentration or concentration-response measures) between the field population and a relevant susceptible control population where available or historical field populations and/or lack of a statistically significant difference in measures between field population and a resistant positive control population<sup>†</sup>; and

<sup>†</sup> If a resistant positive control population is not available or accessible, Pioneer must consult with EPA prior to initiating bioassays and work to develop an appropriate resistant positive control population.

- ii. Either a lack of a statistically significant difference in the same measures of the field population exposed to diet containing the Bt protein (diagnostic concentration) and diet not containing the Bt protein and/or lack of a statistically significant difference in measures between the field population and a resistant positive control population, or lack of a statistically significant concentration and/or lack of a statistically significant difference in concentration response between the field and a resistant positive control population<sup>†</sup>.
- 3) Mitigation, as detailed in section e(2)(c) below, is required for any CRW population that meets EPA's resistance criteria above, unless the circumstances described below are applicable.
- a. To minimize the potential for incorrectly reaching a conclusion of resistance, another year of CRW adult collections and additional testing is needed to determine resistance if:
    - i. The results of the bioassays are inconclusive (e.g., the results of the statistical analysis are unclear because of low sample sizes) or
    - ii. Another reasonable explanation for the unexpected damage exists (e.g., high pest pressure and/or high plant stress).
  - b. In these cases, Pioneer and EPA will discuss and align on next steps before reaching any resistance conclusion.
  - c. If CRW collections are not possible in the current year or subsequent year due to successful management practices, then no further investigation is needed. The population would be considered "mitigated" meaning, in this case, that the population is suppressed or extirpated for the UXD field. However, EPA recommends that Pioneer continue to be vigilant in areas where CRW populations were successfully mitigated.
  - d. If a UXD field receives non-host crop (e.g., soybean) rotation the following year as described in Section e(2)(a)(2) above, no additional mitigation is subsequently required.

c) Mitigation of CRW Populations Meeting EPA's Resistance Criteria

- 1) For any CRW population found to be resistant under EPA's criteria described in section e(2)(b) above, Pioneer must take the following steps:
- a. Pioneer must inform EPA of the results of the bioassays as soon as possible, but at least within 30 days if measures are triggered.
  - b. The mitigation action area (MAA) is defined as the growers' farming operation up to a ½ mile radius from the damaged site that produced the resistant population.
  - c. Within 30 days of informing EPA of the results of the bioassays, Pioneer must notify state extension agents and crop consultants who operate within the county in which resistance was identified. Information shared must include identification of the county in which resistance was detected and trait(s) affected.
  - d. Within the MAA, Pioneer must do the following:

- i. Prior to finalizing the grower's seed order for the following season, inform the affected grower and other registrants that hold registrations containing the affected trait. Pioneer must also inform neighboring growers if those growers are customers of Pioneer. Information shared must include identification of the county in which resistance was detected and trait(s) affected;
  - ii. Discontinue sales/planting of single trait product containing the compromised trait until resistance has been demonstrated to have been mitigated;
  - iii. Pioneer must monitor the resistant population in the MAA, as long as grower remains a customer of the company, until mitigation has been demonstrated as described in part e below unless otherwise agreed with EPA.
  - iv. Require any pyramids sold by Pioneer containing the compromised trait be planted with a 20% refuge until resistance has been demonstrated to have been mitigated. Other Bt registrants selling pyramided products in the MAA are encouraged, but cannot be required by this term of registration, to follow suit;
  - v. For Pioneer's affected customer's field(s), the mitigation goal is to control the resistant CRW population. Within the MAA Pioneer shall encourage the use of "Mitigation Practices" including:
    1. Primary option: Rotation to a non-host crop (e.g., soybean);
    2. Secondary options:
      - a. Use of pyramided Bt corn products with multiple CRW PIP traits;
      - b. Use of different single-CRW PIP traits (i.e., an alternative CRW-active PIP);
      - c. Use of non-Bt corn or non-CRW protected corn (with/without soil-applied insecticide);
    3. Tertiary options:
      - a. If additional pest management need is determined beyond the secondary options listed above, additional CRW control tools (e.g., soil insecticides, seed-applied insecticides, chemigation) should be used.
      - b. Use of foliar applications to control adults (when appropriate economic thresholds have been met) may be used in conjunction with one or more of the above;
- e. A resistant CRW population in the MAA will be considered mitigated if one of the following criteria is met:
  - i. Corn fields within the MAA are rotated to a non-host crop (e.g. soybean) for one growing season.
  - ii. After implementation of mitigation practices (part d.v above), resistance monitoring (sampling) is conducted but few CRW are found (i.e., <0.1 adults per plant) and environmental conditions (e.g., weather) are unlikely to be responsible for the lack of adult CRW presence. If environmental conditions are a factor, then monitoring should continue for another season.

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- iii. After implementation practices (part d.v above), resistance monitoring (sampling) is conducted, CRW are found and collected, and bioassays (section e(2)(b)(2) above) show that the population susceptibility to the identified trait has returned to baseline levels.
  - f. The mitigation actions in part d above can be lifted, and growers can resume the use of Optimum® TRIsect™ corn as a primary tool for CRW management in the MAA, only when Pioneer demonstrates that successful mitigation as described in part e above has been achieved.
- 2) Based on further research to understand CRW resistance to Bt PIPs, EPA will consider refinements to the resistance mitigation program. Such research may include characterizing the genetics of resistance (e.g., number of genes, functional dominance, mechanism of resistance, and cross-resistance) and the biology of resistant insects (e.g., fitness in the presence and absence of the product), and other control tactics.

**f. Annual Reporting Requirements for Optimum® TRIsect™ corn**

The following annual reports must be submitted, provided the registration is extended beyond the current registration expiration date.

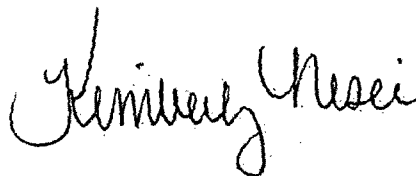
- 1) Compliance Assurance Plan: Compliance Assurance Program activities, including IRM Grower Survey results and on-farm assessment results for the prior year and plans for the compliance assurance program for the current year, on or before January 31<sup>st</sup> each year.
- 2) Insect Resistance Monitoring Results (Cry1F only): results of monitoring and investigations of damage reports, August 31<sup>st</sup> of each year.
- 3) IPM Stewardship Program (mCry3A only): Activities conducted under the IPM stewardship program, including an anonymous survey of grower practices, adoption levels of the various crop rotation options (if employed) and other elements of the stewardship program, on or before January 31<sup>st</sup> of each year.
- 4) Unexpected Damage Investigations (mCry3A only): Activities related to investigations of unexpected damage (UXD), including number and location of UXD cases, insect sampling, bioassays, and final disposition of UXD fields from the most recent and previous corn growing seasons, on or before November 30<sup>th</sup> of each year.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of this product constitutes acceptance of these conditions.

This amendment does not affect the last approved label (dated September 28, 2015) for this product.

Sincerely,

Mr. Jamie Staley  
EPA Reg. No. 29964-13

A handwritten signature in cursive script, reading "Kimberly Nesci".

Kimberly Nesci, Chief  
Microbial Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511P)